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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,691	09/09/2003	Kevin J. Kayscr	GTI-1512	3536

7590 07/13/2004
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EXAMINER

KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/658,691

Applicant(s)

KAYSER ET AL.

Examiner

Rosanne Kosson

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 and 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

In response to the restriction requirement, Applicants' election with traverse of Group X in the reply filed on May 27, 2004 is acknowledged. Claims 1-19 and 22-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicants timely traversed the restriction/election requirement in the reply filed on May 27, 2004.

The traversal is on the ground(s) that the groups are related by having in common the feature of selective cleavage of C-N bonds. This is not found persuasive because the selective cleavage of C-N bonds encompasses numerous different chemical and enzymatic reactions that occur in vitro and in vivo. This is, therefore, not a feature that would allow any two of the groups listed in the restriction/election action to form one invention. The claims of Groups I-VIII are drawn to different methods involving different substrates and different microorganisms that possess different genes and different metabolic pathways. The claims of Groups IX-XII are drawn to different products (an operon, a bacterial culture, a DNA sequence and a bacterium deposited with the ATCC). Consequently, substantial burden results from the separate searches, in particular the literature searches, required for each group, as the search for one invention would not cover the search for a different invention. These products would be expected to have distinct morphological, functional and physiological properties, as evidenced by their divergent classifications, processes of making and processes of using. A reference found in one search that anticipates or renders obvious a particular

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invention may or may not, with no predictability, anticipate or render obvious a different invention as claimed.

With respect to Applicants' arguments regarding generic claims, claim 8 is not a generic claim. It recites combining genes to form an operon, inserting the operon into a host and contacting the host with carbazole, but does not define a genus. The organisms recited for use in each of Groups III-VIII are different organisms, each with its own set of genes, encoded enzymes and metabolic pathways. The methods of the inventions of Groups III-VIII are directed to separate and distinct methods, and the corresponding claims do not recite species of a generic claim. A dependent claim is not necessarily or automatically a species claim with respect to the claim from which it depends. Therefore, although Groups III-VIII contain claim 8 and claims which depend from claim 8, these claims do not necessarily or automatically have a genus-species relationship. Claim 20, which recites a bacterial culture comprising a biochemical pathway that selectively cleaves C-N bonds is so broad that it encompasses all bacteria. Thus, it is not an allowable generic claim and does not entitle Applicants to claims to additional species in other groups of inventions. The restriction/election requirements in the Office Action of May 14, 2004 are maintained.

The rules clearly provide for restriction of inventions when multiple inventions are claimed (see MPEP 802). Thus, it is respectfully submitted that unless Applicants are willing to concede that all of the claimed methods are obvious uses of the claimed product and that all of the non-elected claimed products are rendered obvious by the elected invention, restriction of the claimed inventions is clearly proper.

Because the requirement is still deemed proper, it is therefore made FINAL.

Consequently, the claims of Group X, claims 20 and 21, are examined for patentability, and claims 1-19 and 22-24 have been withdrawn from prosecution.

Information Disclosure Statement

The information disclosure statement filed June 6, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, and copies of the references that were received have been considered, but copies of certain references referred to therein are not present and have not been considered. Copies of the following are not present in the file: sheet 1, items AR and AT (Shepherd and Nojiri), sheet 2, item AR (Kirimura), sheet 4, item AT (Loh), sheet 8, items AR and AS (Ellis and Maidak). Applicants may wish to send an IDS with copies of these references in order to have them considered.

Claim Objections

Claim 21 is objected to because of the following informalities: SEQ ID NOS. have been omitted from the claim and should be inserted to identify corresponding sequences in the Sequence Listing. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 20 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This claim is drawn to an organism per se which is found in nature and is, therefore, unpatentable to Applicants. Consequently, the claim does not embody patentable subject matter as defined in 35 USC §101 (see, e.g., *American Wood v. Fiber Disintegrating Co.*, 90 US 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 US 1 (1931); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 US 127 (1948); *Diamond v. Chakrabarty*, 206 USPQ 193 (1980)). It is suggested that Applicants use the language “a biologically pure culture” in connection with the strain to identify a product that is not found in nature.

A bacterial culture comprising a biochemical pathway suitable for selective cleavage of C-N bonds, as recited in claim 20, is a product of nature because all naturally occurring bacterial cultures have metabolic processes in which C-N bonds are selectively cleaved, e.g., protein digestion, DNA replication and RNA processing and degradation. It is suggested that Applicants use the language “a biologically pure culture” in connection with the strain to identify a product that is not found in nature. Therefore, a holding of non-statutory subject matter is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Because a microorganism is recited in the claim, it is essential to the invention recited in that claim. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism, and it is not apparent if the microorganism is readily available to the public. It is noted that Applicants have deposited the organism, but there is no indication in the specification as to public availability.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicants are directed to 37 CFR § 1.807(b), which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

Applicants are also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Sierra (U.S. 3,276,840) or by Sato et al. (J Bacteriology 179(15):4841-4849, 1997) or by Outtrup (Outtrup I, U.S. 5,856,167) or by Outtrup et al. (Outtrup II, U.S. 5,888,797) or by Outtrup et al. (Outtrup III, U.S. 5,928,929). Claim 20 recites a bacterial culture comprising a biochemical pathway suitable for selective cleavage of C-N bonds. Bacteria that produce enzymes that selectively cleave C-N bonds are well known in the field of bacteriology. For example, Sierra discloses *Bacillus subtilis* and *Clostridium* genera cultures containing subtilisin, a protease that selectively breaks down proteins in spores to allow germination (see column 1, lines 59-65, column 2, lines 27-34, and column 2, line 71, to column 3, line 32). Subtilisins (EC 3.4.21.62, classification created 1992) are known to hydrolyze proteins with broad specificity for peptide bonds (see enclosed record from Enzyme Nomenclature at <http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/4/21/62.html>).

Additionally, Sato discloses a culture of *Pseudomonas* sp. strain CA10, which selectively cleaves C-N bonds in carbazole (see Abstract and Figure 1, p. 4842).

Outtrup I discloses a *Bacillus* sp. culture from which a previously unknown alkaline protease, suitable for breaking down protein residues in laundry, may be derived (see column 1, lines 10-42, column 2, lines 24-29, and column 3, lines 17-22).

Outtrup II also discloses a *Bacillus* sp. culture from which a previously unknown alkaline protease, suitable for breaking down protein residues in laundry, may be derived (see column 1, lines 14-37, column 2, lines 54-61, and column 4, lines 2-6).

Outtrup III discloses a third *Bacillus* sp. culture from which a previously unknown alkaline protease, suitable for breaking down protein residues in laundry, may be derived (see column 1, lines 15-38, column 2, lines 54-63, and column 3, lines 56-60).

The disclosures of Sierra, Sato and Outtrup I-III read on claimed invention. Thus, in view of Sierra or Sato or Outtrup I or Outtrup II or Outtrup III, a holding of anticipation is required.

Claims 20 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Kilbane et al., Biochem Biophys Res Comm 297(2):242-248, available online September 4, 2002. The cited reference antedates Applicants' priority date of September 10, 2002, and the authors are a different inventive entity than the inventors in the instant application. The reference discloses a *Sphingomonas* sp. culture designated GTIN11 that degrades carbazole. A partial sequence for the carbazole degradation operon in this bacterium, containing, i.a., a carAa gene and a carAc gene, was published under GenBank Accession No. AF442494 (see first full paragraph on p. 244). This disclosure reads on claim 20 and appears to be the same microorganism as recited in claim 21 (see specification, p. 7, lines 2-7). Thus, a holding of anticipation is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

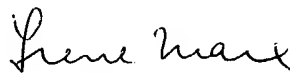
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk
2004-07-07



IRENE MARK
PRIMARY EXAMINER